Influvac Suspension for Injection

2026 SH

Package Insert

INFLUVAC 2026

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus surface antigens (inactivated) (haemagglutinin and neuraminidase) of the following strains*:

- A/Missouri/11/2025 (H1N1)pdm09-like strain (A/Switzerland/6849/2025, IVR-278)	15 micrograms HA**
- A/Singapore/GP20238/2024 (H3N2)-like strain (A/Singapore/GP20238/2024, IVR-277)	15 micrograms HA**
- B/Austria/1359417/2021-like strain (B/Austria/1359417/2021, BVR-26)	15 micrograms HA**

per 0.5 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks

** haemagglutinin.

This vaccine complies with the World Health Organisation (WHO) recommendation (southern hemisphere) and competent authority decision for the 2026 season. For a full list of excipients see section 5.1.

Influvac® 2026 may contain traces of eggs (such as ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin, which are used during the manufacturing process (see section 3.3).

2. PHARMACEUTICAL FORM

Suspension for injection in prefilled syringe; a colourless clear liquid, filled in single-dose syringes.

3. CLINICAL PARTICULARS

3.1. Therapeutic indications

Prophylaxis of influenza, especially those who run an increased risk of associated complications.

Influvac® is indicated in adults and children from 6 months of age.

The use of Influvac® should be based on official recommendations.

Vaccination is particularly recommended for the following categories of patients, depending on national immunization policies:

- Persons aged ≥ 65 years, regardless their health condition.
- Adults and children with chronic disorders of the pulmonary or cardiovascular systems, including asthma.
- Adults and children with chronic metabolic diseases such as diabetes mellitus.
- Adults and children with chronic renal dysfunction.
- Adults and children with immunodeficiencies due to disease or immunosuppressant medication (e.g., cytostatics or corticosteroids) or radiotherapy.
- Children and teenagers (6 months – 18 years) who receive long-term acetylsalicylic acid containing medication and might therefore be at risk for developing Reye's syndrome following an influenza infection.

3.2. Posology and method of administration

Posology

Adults: 0.5 ml.

Paediatric population

Children from 36 months onwards: 0.5 ml.

Children from 6 months to 35 months: Clinical data are limited.

Dosages of 0.25 ml or 0.5 ml may be given, for detailed instructions on administering a 0.25 ml or 0.5 ml dose, see section 5.6. The dose given should be in accordance with existing national recommendations.

For children, who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Children less than 6 months: the safety and efficacy of Influvac® in children less than 6 months have not been established. No data are available.

Method of Administration

Immunisation should be carried out by intramuscular or deep subcutaneous injection. Precautions to be taken before handling or administrating the medicinal product: For instructions for preparation of the medicinal product before administration, see section 5.6.

3.3. Contraindications

Hypersensitivity to the active substances, to any of the excipients listed in section 5.1 or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin. Immunisation shall be postponed in patients with febrile illness or acute infection.

3.4. Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine. Influvac® 2026 should under no circumstances be administered intravascularly. As with other vaccines administered

intramuscularly, Influvac® should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these subjects.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Influvac® is not effective against all possible strains of influenza virus. Influvac® is intended to provide protection against those strains of virus from which the vaccine is prepared and to closely related strains.

As with any vaccine, a protective immune response may not be elicited in all vaccines. Antibody response in patients with endogenous or iatrogenic immunosuppression maybe insufficient. Interference with serological testing: see section 3.5.

This medicine contains less than 1mmol sodium (23 mg) per dose, i.e essentially 'sodium-free'. This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e essentially "potassium-free".

3.5. Interaction with other medicinal products and other forms of interaction

Influvac® 2026 may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified. The immunological response may be diminished if the patient is undergoing immunosuppressant treatment. Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false-positive reactions could be due to the IgM response by the vaccine.

3.6. Fertility, pregnancy and lactation

Pregnancy Inactivated influenza vaccines can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of influenza vaccine do not indicate any adverse foetal and maternal outcomes attributable to the vaccine. Breastfeeding Influvac® 2026 may be used during breastfeeding. Fertility No fertility data are available

3.7. Effects on ability to drive and use machines

Influvac® 2026 has no or negligible influence on the ability to drive and use machines.

3.8. Undesirable effects

a. Summary of safety profile

The most frequently reported adverse drug reactions following use of Influvac® are local and/or systemic reactions such as injection site pain or fatigue and headache. Most of these adverse reactions are of mild to moderate intensity. These reactions usually disappear within 1-2 days without treatment. In rare cases, allergic reactions may evolve to shock, angioedema (see section 3.4)

b. Tabulated summary of adverse reactions

The following undesirable effects have been observed during clinical trials or are resulting from post-marketing experience with the following frequencies: very common (1/10); common (1/100, <1/10); uncommon (1/1,000, <1/100); and not known (adverse reactions from post-marketing experience; cannot be estimated from the available data).

Adverse Reactions Reported with Influvac

MedDRA System Organ class	**Very common 1/10**	**Common 1/100, <1/10**	**Uncommon 1/1,000, <1/100**	**Not Known[a] (cannot be estimated from the available data)**
Blood and lymphatic system	-	-		Transient thrombocytopenia transient lymphadenopathy
Immune system disorders	-	-		Allergic reactions, in rare cases leading to shock angioedema
Nervous system disorders	-	Headache[b]		Neuralgia, paraethesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barre syndrome
Vascular disorders	-			Vasculitis associated in very rare cases with transient renal involvement
Skin and subcutaneous tissue disorders		Sweating[b]		Generalised skin reactions including pruritus urticaria or non-specific rash
Musculoskeletal and connective tissue disorders		Myalgia, arthralgia[b]		
General disorders and administration site conditions		Fever, malaise, shivering, fatigue, Local reactions: redness, swelling, pain, ecchymosis, in duration[b]		

[a] Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure

[b] These reactions usually disappear within 1-2 days without treatment.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

3.9. Overdose

Overdosage is unlikely to have any untoward effect.

4. PHARMACOLOGICAL PROPERTIES

4.1. Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC Code: J07BB02.

Seroprotection is generally obtained within 2 to 3 weeks. The duration of post vaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

4.2. Pharmacokinetic properties

Not applicable.

4.3. Preclinical safety data

Not applicable.

5. PHARMACEUTICAL PARTICULARS

5.1. List of excipients

Potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate,sodium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate and water for injections.

5.2. Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

5.3. Shelf-life

1 year.

5.4. Special precautions for storage

Store in a refrigerator (2°C to 8°C). Do not freeze. Store in the original package in order to protect from light.

5.5. Nature and contents of the container

0.5 ml suspension for injection in prefilled syringe with or without needle (glass, type I) pack of 1 or 10.

5.6. Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use. Shake before use. Inspect visually prior to administration.

For the administration of a 0.25 ml dose from a single dose 0.5 ml syringe, push the front side of the plunger exactly to the edge of the mark so that half of the volume is eliminated; a volume of 0.25 ml of the vaccine remains in the syringe, suitable for administration. See also section 3.2.

Any unused product or waste material should be disposed of in accordance with local requirements.

6. MANUFACTURER

Abbott Biologicals B.V.
Veerweg 12
8121 AA Olst
The Netherlands

7. DATE OF APPROVAL/REVISION OF THIS TEXT

Feb 2026

RDCCDS000650/2

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2025/ 2026 NH

Package Insert

INFLUVAC® 2025/2026

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus surface antigens (inactivated) (haemagglutinin and neuraminidase) of the following strains*:

- A/Victoria/4897/2022 (H1N1) pdm09-like strain (A/Victoria/4897/2022, IVR-238)	15 micrograms HA**
- A/Croatia/10136RV/2023 (H3N2)-like strain (A/Croatia/10136RV/2023, X-425A)	15 micrograms HA**
- B/Austria/1359417/2021-like strain (B/Austria/1359417/2021, BVR-26)	15 micrograms HA**

per 0.5 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks

** haemagglutinin.

This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and competent authority decision for the 2025/2026 season. For a full list of excipients see section 5.1.

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Apr 2025

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